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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/720,970 | 01/03/2001 | Hideaki Nomura | 081356/0156 | 8299 |

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| EXAMINER | |
|---|---|
| GOLLAMUDI, SHARMILA S | |
| **ART UNIT** | **PAPER NUMBER** |
| 1616 | |

DATE MAILED: 10/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. 09/720,970 | Applicant(s) NOMURA ET AL. | |
|---|---|---|---|
| | Examiner Sharmila S. Gollamudi | Art Unit 1616 | |

*-- The MAILING DATE of this communication appears on th cov r sheet with the correspondence addr ss --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *15 August 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,2,6-9 and 13-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,6-9 and 13-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

Receipt for extension of Time and Amendment B received on August 15, 2002 is acknowledged. Claims 1-2, 6-9, and 13-20 are included in the prosecution of this application.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

**Claims 1, 2, 6, 7, 9, 13-17, and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 93/24149 in view of WO 90/09780.**

WO 93/24149 discloses a powder composition containing HPMC, chitosan in instant range, and a medicament (proteins, etc.) (Note example 1 and page 5 and 6). The reference teaches the composition for the application to the nasal mucosa (pg. 1, paragraph 1).

WO 93/24149 does not teach the instant cationic polymer.

WO 90/09780 discloses an active agent such as insulin and a polycationic substance for administration to the mucosa (Note abstract and example 5). The reference teaches the use of polycationic substances improve the formulation since it eliminates the need for additional enhancers (pg. 3, second paragraph). The polycationic substances that are suitable are chitosan, polyaminoacids, co-polymethacrylates, GAFQUAT, etc. (pg. 5). The composition is taught in a powder or

microsphere form (pg. 3, last paragraph). The reference teaches a gelling agent for increased viscosity to retain the formulation on the mucosa (pg. 6, paragraph 2). Further, prior art in which a high molecular drug and a gelling agent (hydroxyethyl cellulose) are administered nasally is disclosed (pg. 2, second paragraph).

It would have been obvious to one of ordinary skill in the art at the time the invention was made use co-polymethylacrylates in WO 93/24149's powder composition since WO 90/09780 teaches the equivalency of chitosan and the polymethacrylates. One would be motivated to do so with the expectation of similar results since both chitosan and polymethacrylates are polycationic substances that improve the formulation as taught by WO 90/09780.

***Response to Arguments***

Applicant argues that WO 93/24149 does not anticipate the instant invention since the instant cationic polymers are not taught. Applicant argues that WO teaches the inclusion of nonionic cellulose. It is argued that WO does not teach "that this composition is formulated so that the absorption of the active ingredient through the mucosa is accelerated."

Applicant's arguments have been fully considered and although the amendment obviates the anticipation of the instant invention, WO is used in an obviousness-type rejection as set forth above. The examiner points out that the instant claim language does not exclude other components, i.e. nonionic cellulose. Further, the examiner points out that the instant claims are product claims and the intended use or the motivation for formulating the composition, i.e. accelerating absorption, does not hold patentable

weight. The prior art teaches the critical components, a high molecular weight drug and a cationic polymer. The examiner relies on the secondary reference to teach the equivalence between the cationic polymer used in WO 93/24149 and the instant polymers. Additionally the applicant has not provided any unexpected results using the instant polymers. Therefore, the claims are rejected as *prima facie* obvious.

**Claims 1, 2, 7, 9, 13-17, and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 90/09780.**

WO 90/09780 discloses an active agent such as insulin and a polycationic substance for administration to the mucosa (Note abstract and example 5). The reference teaches the use of polycationic substances improve the formulation since it eliminates the need for additional enhancers (pg. 3, second paragraph). The polycationic substances that are suitable are polyaminoacids, co-polymethacrylates, etc. (pg. 5). The composition is taught in a powder or microsphere form (pg. 3, last paragraph). The reference teaches a gelling agent for increased viscosity to retain the formulation on the mucosa (pg. 6, paragraph 2). Further, prior art in which a high molecular drug and a gelling agent (hydroxyethyl cellulose) are administered nasally is disclosed (pg. 2, second paragraph).

WO 90/09780 does not exemplify the instant cationic polymers.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use any of the suitable cationic polymers taught by WO 90/09780 with the reasonable expectation of similar results since the reference suggests the use of several interchangeable polycationic substances.

***Response to Arguments***

Applicant argues that WO 90/09780 does not teach a powdered preparation containing a high molecular weight medicine or the specific cationic polymers. The applicant argues that the instant polymers have improved absorption over the prior art's chitosan and DAE-dextran.

Applicant's arguments have been fully considered but they are not persuasive. Although WO 90/09780 does not exemplify the composition in a powder form, the examiner points out that the rejection is based on obviousness; therefore the prior art does not have exemplify every element of the instant invention. The examiner points to page 9, the reference teaches the formulation is suitable for solid dosage form such as tablets, pellets, etc. Further, the reference teaches the use of methacrylate copolymers on page 9. The examiner points out that the instant claims are product claims and the intended use of the composition does not hold patentable weight. A structural difference between the claimed invention and the prior art must be established in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Therefore, since the recited "powder preparation" is a solid formulation and WO teaches the composition formulated as a solid dosage, WO reads on instant claims as an obviousness-type rejection. Lastly, the applicant as not provided any unexpected results using the instant polymers. Example 18 and 19 of instant specification also teach the use the prior art's chitosan and DEAE-dextran as cationic polymers.

**Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 93/24149 in view of WO 90/09780 in further view of JP 406065090 or WO 90/09780 in view of JP 406065090.**

As set forth above, WO 93 and WO 90 teach compositions containing cationic polymers and medicines such as proteins.

The references do not teach the specific protein G-CSF.

JP teaches G-CSF in a nasal formulation for curing leucopenia.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to G-CSF in WO's composition to treat leucopenia as taught by JP. One would be motivated to do so with the expectation of similar results since JP teaches the instant protein is suitable for nasal administration.

**Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 93/24149 in view of WO 90/09780 in further view of Stanton et al (5807552 ) or WO 90/09780 in view of Stanton et al (5807552 )**

As set forth above, WO 93 and WO 90 teach compositions containing cationic polymers and medicines such as proteins. WO 90/09780 teaches the inclusion of vaccines (page 7).

The references do not specify a protein that is conjugated to a hapten.

Stanton et al teach the use of hapten-carrier (protein) molecules for use in human and animal prophylaxis. Stanton teaches the hapten-carrier molecules illicit immune response and function as vaccine (col. 3, lines 10-40).

It would have been obvious to one of ordinary skill in the art at the time the invention was made incorporate hapten-carrier (protein) molecules in WO's composition to illicit immune response and function as a vaccine as taught by Stanton et al. One would be motivated to incorporate a specific medicine depending on the symptoms to be treated.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 703-305-2147. The examiner can normally be reached on M-F (7:30-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 709-3080196.

SSG

October 23, 2002

MICHAEL G. HARTLEY
PRIMARY EXAMINER